REMARKS

Claims 1-19 are pending. Claims 1-7, 9, 15, and 17 have been examined and are presently under consideration. Claims 11-14 and 19 have been withdrawn as directed to a non-elected invention. Claims 8, 10, 16, and 18 are directed to non-elected species of the elected invention and have not yet been examined.

Claim 1 has been amended to emphasize that it is the finished, as applied hydrogel layer that is subjected to treatment with electromagnetic radiation and immobilized to the surface of the polymer substrate. Support is found, for example, in the specification at page 3, lines 8-11: "The invention thus provides for the immobilization or fixing of an already finished hydrogel on polymer surfaces, in contrast to the method common in the state of the art of producing a hydrogel from corresponding monomers." Further, from original claim 1 is clear that the hydrogel-forming polymer "is applied to the surface of a polymer substrate" and therefore must be immobilized to the surface of the substrate when the photoinitiator is activated. Claim 2 has been amended for clarity. No new matter has been added.

The claims under consideration have been rejected for alleged anticipation or obviousness. The rejections are traversed, and their reconsideration and withdrawal are respectfully requested in view of the remarks below.

Rejection Under 35 U.S.C. 102(b)

Claims 1, 3-7, and 15 are rejected as allegedly anticipated by Swan et al. US 2002/0004140 A1.

Swan discloses a method of forming a polymer layer on a substrate by attaching a base layer of a coating agent and

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polymerizing an upper layer onto the coating layer. The coating agent consists of a low molecular weight (100-1000 MW), nonpolymeric core molecule that possesses one class of photoreactive groups for attachment to the substrate as well as another class of photoreactive groups for attachment to the upper polymer layer. See Swan at [0044] - [0045].

Swan does not teach or suggest the attachment of a hydrogel-forming polymer to a substrate surface, as required by the presently claimed method. In Swan's method, hydrogel-forming polymers are never attached to the substrate directly; instead, Swan forms polymers that are attached to a coating agent. Swan's coating agent forms an interface between the substrate and a separate polymer layer. Swan's coating agent is comprised of core molecules that are expressly nonpolymeric and not larger than 1000 Daltons in molecular weight. Therefore, Swan teaches away from the present invention, in which hydrogel-forming polymers are directly coupled to the polymer substrate surface. The hydrogel-forming polymers required in the claimed method do not satisfy either of the criteria for Swan's coating agent, i.e., being nonpolymeric and being 100-1000 MW.

In most embodiments, Swan applies "polymerizable molecules" (i.e., monomers) to the coating agent. See Swan at [0069]. These embodiments are readily distinguishable from the claimed methods, which require the use of hydrogel-forming polymers, not monomers, resulting in the immobilization of an already finished hydrogel to the substrate.

In some embodiments, Swan uses "macromers" as the polymerizable material. See Swan at [0079] - [0080]. The Office Action points out at page 3, lines 6-8, that Swan teaches polymerizable groups that include polyvinylpyrrolidinone and

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polyethylene glycol, which are known as hydrogel polymers. While the Examiner has assumed that Swan's further polymerization of macromers is equivalent to Applicants' use of hydrogel-forming polymers, there are at least two important differences: (1) Swan's macromers are immobilized by coupling to the core molecules of Swan's coating agent, not to the substrate directly; and (2) Swan's macromers are further polymerized during the reaction, which has no correlate in the presently claimed method, in which already finished polymers are immobilized onto the substrate. Applicants note that present claim 1 requires that a composition comprising a hydrogel forming polymer "is applied to the surface of a polymer substrate" and that "the finished, as applied hydrogel is immobilized to the surface of the polymer substrate". Emphasis added.

In the Office Action at page 5, last sentence, citation is made to *Ex parte Rubin* for the proposition that merely transposing process steps or splitting one step into two does not provide a patentable distinction over the prior art. However, the presently claimed method cannot be validly viewed as a mere transposition of the steps of Swan. The use of the coating agent of Swan, which the present claims avoid, is the entire point of Swan's patent (thus the title, "Water Soluble Coating Agents Bearing Initiator Groups"). Swan utilizes nonpolymeric coating agents specifically to avoid the issues associated with attaching a polymer to a substrate surface (see discussion below). Swan then, in some embodiments, attaches "macromers" instead of monomers, but never in the absence of the coating agent. It is the coating agent in Swan's method that enables growth and attachment of a polymeric hydrogel material

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to the substrate. Swan characterizes the purpose of his coating agent as to "initiate photopolymerization from the surface" and "to improve the initiation of photopolymerization to grow a polymer from a support surface." Swan at [0010]. Further, Swan states that his invention "provides a method of using a coating agent to form a polymer layer on a support surface, as well as a method of priming a support surface with the coating agent itself." Swan at [0011]. Therefore, the claimed invention cannot be viewed as merely the process of Swan without the coating agent, as the coating agent is essential to Swan's process. Furthermore, the claimed invention also cannot be viewed as the process of Swan in which polymerization is performed prior to immobilization, because even if the steps are performed in a different order, Swan produces a different structure than the claimed method. Swan polymerizes hydrogel-forming monomers or macromers to a coating agent, not to the surface of a polymer substrate.

The presently claimed invention has several additional properties that further distinguish it from prior methods. First, the resulting coatings have low toxicity due to the presence of extremely low residual levels of monomers used in the polymerization process. The polymerization and cross-linking of monomers in the formation of hydrogels involves the production of radicals, and nearly all such monomers are cancerogenic. In contrast, the very low levels of toxic monomers resulting from the present coating method is a particular advantage for coatings of medical products through which blood flows and is then recycled to the patient's body. By coating with already finished hydrogel-forming polymers in the present method, the monomer content is remarkably reduced in

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comparison to hydrogels that are formed from monomers in the coated product. The present invention offers the possibility to use finished hydrogels for the coating; such hydrogels are largely reacted to completion, and their monomer content has been measured as being extremely low.

Second, a composition comprising already finished hydrogel-forming polymers possesses a better viscosity and stability than an unpolymerized or incompletely polymerized solution, resulting in better physical surface adhesion and a smoother coating than is possible when using a monomer solution.

Finally, as explained in the introductory part of the present application, the immobilization of finished hydrogels on polymeric surfaces is not at all simple, due to the availability of fewer binding points on the surface to achieve a stable immobilization. In the prior art, immobilization of finished hydrogel-forming polymers has been realized only by gamma-radiation or by means of toxic substances. To the contrary, the process according to the present invention achieves the immobilization of an already finished hydrogel-forming polymer by means of a non-toxic photoinitiator compound and subsequent treatment of the hydrogel-forming polymer layer with lower wavelength electromagnetic radiation.

Thus the cited prior art fails to teach or suggest the method of the present claims. In particular, Swan fails to teach or suggest the immobilization of an already finished hydrogel-forming polymer to the surface of a polymer substrate. The withdrawal of this rejection is respectfully requested.

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Rejections Under 35 U.S.C. 103(a)

Claim 2 is rejected as allegedly obvious over Swan et al. (US 2002/0004140 A1). Claim 2 recites the method of claim 1 in which electromagnetic radiation in the range of 170 to 600 nm is used to activate immobilization. The Office Action states that Swan teaches irradiation in the 330 - 340 nm range, and alleges that the range recited in claim 2 would be the result of routine optimization. However, as discussed above, Swan fails to teach or suggest all the limitations of the base claim. In particular, Swan fails to teach or suggest the immobilization of an already finished hydrogel-forming polymer to the surface of a polymer substrate. Therefore, Swan fails to support a *prima facie* obviousness rejection. The withdrawal of this rejection is respectfully requested.

Claims 9 and 17 are rejected as allegedly obvious over Swan in view of Kondo et al. (JP 54060386A). Claims 9 and 17 recite the use of nicotinic acid amide as initiator. The Office Action admits that Swan does not teach such an initiator, and alleges that Kondo teaches nicotinamide derivatives and nicotinamide itself as the unsubstituted form of General Formula 1. However, as discussed above, Swan fails to teach or suggest all the limitations of the base claim, and this defect is not remedied by Kondo. In particular, Swan and Kondo, taken either separately or combined, fail to teach or suggest the immobilization of an already finished hydrogel-forming polymer to the surface of a polymer substrate. Therefore, the combination of Swan and Kondo fails to support a *prima facie* obviousness rejection. The withdrawal of this rejection is respectfully requested.

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The Examiner is encouraged to telephone the undersigned attorney to discuss any matter which would expedite allowance of the present application.

Respectfully submitted,

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